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| APPLICATION NO.  | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|--|-----------------|----------------------|--------------------------|------------------|
| 10/721,034   | 11/24/2003      | T. Douglas Mast      | END-5042                 | 4797             |
| 27777  | 7590 01/25/2005 |                      | EXAMINER                 |                  |
| PHILIP S. JOHNSON  |                 |                      | JAWORSKI, FRANCIS J      |                  |
| JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |                 |                      | ART UNIT                 | PAPER NUMBER     |
|  |                 |                      | 3737                     |                  |
|  |                 |                      | DATE MAIL ED: 01/25/2005 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| ,   | Application No.   | Applicant(s)     |  |  |  |  |
|---|---|------------------|--|--|--|--|
| Office Action Commence  | 10/721,034  | MAST, T. DOUGLAS |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit         |  |  |  |  |
|   | Jaworski Francis J.   | 3737             |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                  |  |  |  |  |
| Status  |   |                  |  |  |  |  |
| 1) Responsive to communication(s) filed on 0730   | ) Responsive to communication(s) filed on <u>07302004</u> .   |                  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |                  |  |  |  |  |
| •—  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |                  |  |  |  |  |
| Disposition of Claims   |   |                  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-32</u> is/are pending in the application.   |   |                  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |                  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |                  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-32</u> is/are rejected.   |   |                  |  |  |  |  |
|   | 7) Claim(s) is/are objected to.   |                  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |                  |  |  |  |  |
| Application Papers  |   |                  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                  |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>11242003</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.   |   |                  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |                  |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |                  |  |  |  |  |
|   |   |                  |  |  |  |  |
| Attachment(s)   |   |                  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date  |   |                  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07302004</u> .  5) Notice of Informal Patent Application (PTO-152) 6) Other:  |   |                  |  |  |  |  |

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- [ Parenthesized claim numbers pertain to the specific claim or claims being addressed by the immediately preceding rejection argument.]

Claims 1 –4, 9- 10, 16 – 19, 23 – 24, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Okazaki (US5005580) which teaches receiving ultrasound imaging signals during first and second time periods into 20a with processing and subtraction therebetween in 20b such that a subtraction image 26 of Fig. 6 is formed which image tracks discrete increments of medical therapy by kidney stone or calculus destruction including through the completion of the treatment, see col. 5 line 46 – col. 6 line 2. The context indicates that the method is practiced all the way from a baseline image of a treated region in its anatomic surroundment prior to treatment through just sufficient completion of treatment as determined from the succession of differential images.

(Claims 1 -4, 9 - 10, 16 - 19, 23 - 24)

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Such paired images are subtracted in an iteration which incrementally tracks treatment during its course. (claim 30).

Claims 1-4, 9-10, 16-19, 23-24, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Lizzi et al (US6533726) which teaches receiving ultrasound imaging signals (Fig. 3 elements 310, 320, 330) during first and second and third time periods, and processing and subtracting the signals (340, 345) and generating an indication therefrom about the effect of the medical diathermy treatment in causing transitory or permanent tissue changes within the anatomic surroundment up to and including treatment termination and subsequent to an initial baseline reading. (Claim 1-4, 9-10, 16-19, 23-24).

Again, such paired images are subtracted in an iteration which incrementally tracks treatment during its course. (Claim 30).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim1 above, and further in view of Cain et al (US5590657).

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Whereas the former are silent as to motion compensation, it would have been obvious in view of the latter cols. 5-6 to compensate for phase aberration effects by a phase compensation function in order to re-focus the ultrasound imaging or treatment on the desired target volume in the event of movement within the target area. (Claim 5).

Claims 6-7, 11- 12, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim1 above, and further in view of Dory (US5354258). Whereas the former are silent as to output scaling, it would have been obvious in view of the latter to perform scaling by element 74 on the ultrasound difference image signal (output of 7) in relation to the initial image signal S2, Since Dory is also tracking the differential tissue image as representing the progress of the treatment and scaling allows blending with the very initial anatomic or B-mode image as a second image type so that the absolute progress of the therapy can be tracked. (Claims 6, 11 - 12, 20).

The use of power scaling would have been obvious since Lizzi et al is concerned with attenuation changes in the tissue which is a power measurement (see col. 5 top); also Dory col. 5 lines 55-68 is concerned with power absorption by tissues (Claims 7, 21).

Claims 8, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim 1 above, and further in view of Geiser et al (US6106470). The former are silent as to spatial filtering. However it would have been obvious in view of the latter to provide at least some spatial filtering in post-processing

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an image in general for display in order to reduce graininess by using local average values. (Claim 8).

Claims 13- 15 and 25 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim 1 above, and further in view of both Dory as applied with respect to scaling of the difference signal (claim 6) and also Geiser et al as applied with respect to spatial filtering (Claim 8) above, which evidence that both of these features were known in association with ultrasound monitoring of medical treatment of in association with general anatomic ultrasound imaging. (Claims 13, 25, 28 - 29).

In both of the base reverences both a first and second image may be received after the initial treatment as the image differencing system iteratively advances during treatment increments, in essence a repeating of the claim 2 argument supra. (Claims 14, 26).

The base argument against claim 3 that the iteration of differencing proceeds up to the final treatment as a viewing tool of its completion applies here (Claims 15, 27).

Claims 31- 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim 30 above, and further in view of Fujimoto et al (US6540700). Whereas the former are silent as to the sue of signal averaging, it would have been obvious in view of the latter to use signal averages, see col. 18 line 60 – col. 19 line 4 as well as col. 20 lines 12 – 23 since this permits small variations in signal levels due to noise to average out such that a small-difference circumstance as is measured during tissue treatment may be more accurately represented. (Claim 31).

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Such averaging would be understood to be a cumulative summation and scaling because one cannot multiply the resulting brightness gradation of the video display.

(Claim 32).

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Fruncia /. Jaworski Primary Examiner